Department of Vermont Health Access
Pharmacy Benefit Management Program
DUR Board Meeting Minutes
April 4, 2017

Board Members:

Present:

Zail Berry, MD	Clayton English, PharmD	Bill Breen, RPh
Alisson Richards, MD	Jocelyn VanOpdorp, PharmD	Louise Rosales, NP
Renee Mosier, PharmD	Patricia King, MD	

Absent:

Staff:

Laurie Brady, RPh, Change HealthCare	MaryBeth Bizzari, RPH, DVHA
Laureen Biczak, DO, Change Healthcare	Jennifer Egelhof, DVHA
	Carrie Germaine, DVHA

Guests:

Shaffee Bacchus, Janssen	Susan Donnelly, Pfizer	Rod Francisco, Sunovion
John Kirby, Sanofi	Kevin Kobylinski, Astellas	Lance Nicholls, Pfizer
Megan Walsh, Abbvie	Joe Ward, Abbvie	Scott Williams, J & J
Folger Tuggle, Bioverativ	David Conak, Sanofi	Leeanna Hoskins, Sarepta
Terry Ashe, Sarepta	Franco Casagrande, Abbvie	Jim Zoller, DMD Family
Laurie Webb, DMD Family	Joanne Wechster, DMD Family	

1. Executive Session:

- An executive session was held from 6:00 p.m. until 6:25p.m.

2. Introductions and Approval of DUR Board Minutes:

- Introductions were made around the table.
- The February meeting minutes were accepted as printed.

3. DVHA Pharmacy Administration Updates: Mary Beth Bizzari, RPh, DVHA

- Scott Strenio will be returning to DVHA in May.

- Aaron French has resigned. His last day is 4/14/17.
- Welcomed new DUR board members Renee Mosier and Joselyn VanOpdorp.

4. Medical Director Update:

- No update at this time.

5. Follow-up Items from Previous Meetings:

- None at this time.

Board Decision: None needed.

6. RetroDUR/DUR: Laurie Brady, RPh, Change Healthcare

- **Introduce: Twice Daily PPI Use**

  Proton pump inhibitors are a class of medications that inhibit production of gastric acid by the parietal cells in the stomach. Developed over 20 years ago, they have been proven in clinical trials to be more effective than H2 antagonists in healing gastric ulcers, duodenal ulcers and esophagitis. Over time, PPIs have become first line therapy to treat these conditions, with indications of treatment that rarely exceed 12 weeks. While treatment of ulcers and esophagitis have guidelines for treatment duration, patients with GERD present a clinical challenge. American College of Gastroenterology guidelines do suggest that patients with GERD who are not free of symptoms after 8 weeks of maximal therapy be continued intermittent or on demand therapy at the lowest effective dose, although the level of evidence is low.

  Many patients use PPIs and H2 blockers chronically to manage symptoms of GERD, sometimes using both together in some fashion. Other patients are using PPIs in bid dosing to treat symptoms. Occasionally, PPIs will be prescribed and dispensed with instructions to take the dose bid for 2 or 3 days to accelerate the effect, but rarely is bid dosing required. Now that PPI medications are available over the counter, there is often chronic, repetitive use for treating heartburn. While indicated for maintenance treatment, the package insert for Prilosec OTC, for example, warns against greater than 14 days of usage. In addition, PPIs have multiple potential drug-drug interactions, are associated with increased risk of atrophic gastritis, hypomagnesemia, diarrhea and C. difficile infections and have been associated with increased risk of osteoporosis-related bone fractures.

  We will use paid, non-reversed Medicaid pharmacy and medical claims date from 2016, excluding members with Part D, VMAP, and Healthy Vermonters coverage. We

will identify members on PPI's twice daily by examining claims data. We will look at the quantity dispensed and compare that to the days' supply, taking the total quantity filled in a 1 year time period to determine the average daily dose. We will compare the percentage of patients using PPI's twice daily to those using once daily or less frequently. We will examine the diagnoses that warrant use of therapy. Additionally, we will identify members who have a prescription for an H2 blocker at the same time they have filled a prescription for a PPI. Due to Medicaid coverage limitations of most over the counter formulations, evaluation of patients who are purchasing or using an OTC product will be limited.

Board Decision: Add pneumonia as one of the diagnoses that is looked at.

- **Data presentation: Long Term use of Skeletal Muscle Relaxants**

  Skeletal muscle pain is a frequent complaint in clinical practice. Numerous treatment options exist, including topical agents, NSAIDs, antidepressants, anticonvulsants, anesthetic and steroid injections, DMARDs and muscle relaxants. Generally, muscle relaxants should be used for 2-3 weeks to treat acute pain, per guidelines and the prescribing information provided by the drug manufacturers. Muscle relaxants have strong anticholinergic properties and can have the unwanted side effects of dizziness, fatigue and impaired cognition. In addition, they have addictive properties and lose effectiveness over time. They generally are not recommended for use in the elderly population and there are many possible drug-drug interactions and side effects that make them potentially dangerous. We proposed to examine the use of skeletal muscle relaxants among Vermont Medicaid members, specifically looking at members who have been prescribed the medications for longer than 30 consecutive days. We were also interested in identifying members who have been co-prescribed opioids or benzodiazepines within the same 30-day period. We looked at members who had prolonged treatment over the course of 90 days and 1 year to see if there was widespread chronic usage among those prescribed muscle relaxants.

  We identified members on the skeletal muscle relaxants (baclofen, carisoprodol, chlorzoxazone, cyclobenzaprine, dantrolene, metaxalone, methocarbamol, orphenadrine, and tizanidine) for more than 30 days within a 90-day period. We identified those who were co-prescribed an opioid or benzodiazepine within the same time period. We identified the prescribers to see if this is a widespread

practice requiring general education outreach or if there are a select number of prescribers who may need intervention.

Change Healthcare feels that after reviewing the data more detail should be pulled and assessed before moving forward with recommended actions. Some possible actions that could be taken would be determining appropriate criteria for the continuation of muscle relaxants beyond duration limitations set or consider a general education strategy for all VT prescribers, as there is widespread prescription of these drugs in the medical community.

Board Decision: The board would like to separate out the utilization by drug to see which ones are being used on a long-term, chronic basis.

7. Review of Newly-Developed/Revised Clinical Coverage Criteria and/or Preferred Products:

- None at this time.

Board Decision: None needed.

8. Clinical Update: Drug Reviews: Laureen Biczak, DO Change Healthcare and Laurie Brady RPh, Change Healthcare

Abbreviated New Drug Reviews:

a) **Basaglar® (insulin glargine)**
   - Included in the Therapeutic Class Review (TCR).

Public Comment: No public comment.

Recommendation: PDL placement and criteria will be recommended when the TCR is reviewed.

Board Decision: Defer decision- to occur with the class review.

Full New Drug Reviews:

a) **Adlyxin® (lixisenatide)**

   - Included in the Therapeutic Class Review (TCR).

Recommendation: PDL placement and criteria will be recommended when the TCR is reviewed.

Board Decision: Defer decision- to occur with the class review.

b) Exondys® 51 (eteplirsen)

- Duchenne Muscular Dystrophy (DMD) is a progressive disease primarily manifested as muscular weakness. It is the most severe form of muscular dystrophy and is a relatively uncommon disease. Because it is inherited in an X-linked recessive pattern, DMD is manifested almost exclusively in boys. Most affected boys are wheelchair bound by the age of 12. Heart and breathing muscles can also be affected in later stages of the disease. Current treatments have been generally aimed at controlling the onset of symptoms and can include corticosteroids, physical therapy, and orthopedic appliances.
- Exondys® 51 is indicated for the treatment of Duchenne muscular dystrophy in patients who have a confirmed mutation of the DMD gene that is amenable to exon 51 skipping. This indication was approved under accelerated approval based on an increase in dystrophin in skeletal muscle observed in some patients treated with Exondys® 51. A clinical benefit of Exondys® 51 has not been established. Continued approval for this indication may be contingent upon verification of a clinical benefit in confirmatory trials. Eteplirsen, the active ingredient of Exondys® 51, is an antisense oligonucleotide of the phosphorodiamidate morpholino oligomer (PMO) subclass. It is designed to bind to exon 51 of dystrophin pre-mRNA, resulting in exclusion of this exon during mRNA processing in patients with genetic mutations that are amenable to exon 51 skipping. Exon skipping is intended to allow for production of an internally truncated dystrophin protein.
- Of those with DMD, only 13% are estimated to carry the mutation that is specifically targeted by Exondys® 51. However, pharmaceutical manufacturers are already looking at additional mutations that would be similarly targeted. Thus, Exondys® 51 likely represents the first of several therapies that will target specific mutations that are present in patients with DMD. Because there is not a specific ICD-10 code for DMD, it is difficult to estimate the number of patients in Vermont that are potential candidates for Exondys® 51. Two methods (national prevalence data and Vermont Medicaid claims data) were used to consider potential utilization of the medication. It is estimated that 1-3 members could be candidates for the drug.
- The clinical studies for Exondys® 51 included extremely small sample sizes and a clinical benefit of treatment, per the 6MWT, was not established. Clinical studies are still ongoing. It is therefore recommended that Exondys® 51

remain non-preferred and require clinical prior authorization to verify diagnosis and use of a stable dose of a corticosteroid for at least 6 months.

Recommendation:

- Add new PDL category Muscular Dystrophy Agents
- Add Exondys® 51 to non-preferred.
    - Clinical criteria
        - The patient must be < 14 years of age AND
        - The patient must have a diagnosis of Duchenne Muscular Dystrophy with a confirmed mutation of the DMD gene that is amenable to exon 51 skipping (results of genetic testing must be submitted) AND
        - The prescriber is, or has consulted with, a neuromuscular disorder specialist AND
        - The dose does not exceed 30mg/kg once weekly AND
        - The patient is currently on a stable corticosteroid dose for at least 6 months AND
        - The patient must be ambulatory (able to walk with or without assistance, not wheelchair bound).
        - **Note:** Initial approval will be granted for 6 months. For re-approval after 6 months, the patient must demonstrate a response to therapy as evidenced by remaining ambulatory (able to walk with or without assistance, not wheelchair bound).

Public Comment: Randy Perrin, Sarepta; Highlighted the attributes of Exondys®51.
Joanne Wechster, DMD family; Discussed personal experience with children with DMD involved in the Exondys®51 trial. Expressed the need for the drug to be covered with no age limits or ambulatory restrictions.
Jim Zoller, DMD family; Discussed personal experience with children with DMD involved in the Exondys®51 trial. Expressed the need for the drug to be covered with no age limits or ambulatory restrictions.
Laurie Webb, DMD family; Discussed personal experience with children with DMD involved in the Exondys®51 trial. Expressed the need for the drug to be covered with no age limits or ambulatory restrictions.

Board Decision: The Board approved the above recommendation removing the age limitation and ambulatory requirement. Change the note to say Initial approval will be granted for 6 months. For re-approval after 6 months, the patient must demonstrate a response to therapy as evidence by continued or improved clinically meaningful function. These recommendations will be presented to the Department of Health Commissioner.

c) Invokamet® XR (canagliflozin/metformin XR)

- Included in the Therapeutic Class Review (TCR).

Recommendation: PDL placement and criteria will be recommended when the TCR is reviewed.

Public Comment: No public comment.

Board Decision: Defer decision- to occur with the class review.

d) Relistor (methylnaltrexone)

- Relistor® is indicated for the treatment of opioid-induced constipation (OIC) in adult patients with chronic non-cancer pain. Methylnaltrexone bromide, the active ingredient of Relistor®, is a mu-opioid receptor antagonist; it is a selective antagonist of opioid binding at the mu-opioid receptor. The ability to cross the blood-brain barrier is restricted, which allows it to function as a peripherally-acting mu-opioid receptor antagonist in tissues such as the GI tract. Thus, this decreases the constipating effects of opioids. It is recommended to discontinue all maintenance laxative treatment prior to starting Relistor®; however, laxatives can be used as needed if there is suboptimal response to Relistor® after 3 days. A subcutaneous injection formulation was previously FDA approved and carries an additional indication of OIC in adults with advanced illness who are receiving palliative care, when response to laxative therapy has not been sufficient. Comparator trials other than placebo-controlled were not found. There is no evidence at this time to support that Relistor® tablets are safer or more effective than the currently available medications.

Recommendation:

- Add Relistor® with quantity limit 3 tablets/day to non-preferred.

- Clinical criteria
    - Relistor Tablets: The patient is current using an opiate for at least 4 weeks AND has documented opioid-induced constipation AND has had a documented side effect, allergy or treatment failure to a 1week trial of at least 2 preferred laxatives from Bulk-Producing Laxative or Osmotic Laxative categories AND has had a documented side effect, allergy, or treatment failure to Amitiza or Movantik.
    - Add "The patient is current using an opiate for at least 4 weeks" to the Movantik criteria.
    - Clarify the current Relistor criteria is for Relistor Injection.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

e) Soliqua® (lixisenatide/insulin glargine)

- Included in the Therapeutic Class Review (TCR).

Recommendation: PDL placement and criteria will be recommended when the TCR is reviewed.

Public Comment: No public comment.

Board Decision: Defer decision- to occur with the class review.

f) Sustol® (granisetron)

- Granisetron, the active ingredient of Sustol®, is a selective serotonin-3 (5-HT3) receptor antagonist. It has little or no affinity for other serotonin receptors. Serotonin receptors of the 5-HT3 type are located peripherally on vagal nerve terminals and centrally in the chemoreceptor trigger zone of the area postrema. During chemotherapy that induces vomiting, serotonin is released, which stimulates 5-HT3 receptors. Sustol® is indicated for use in combination with other anti-emetics in adults for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic chemotherapy (MEC) or anthracycline and cyclophosphamide (AC) combination chemotherapy regimens. Administer 10mg SC in combination with dexamethasone at least 30 minutes before the initiation of MEC or AC combination chemotherapy on day 1 of

chemotherapy and not more frequently than once every 7 days due to the extended-release properties of the formulation. With moderate renal impairment, administer Sustol® on day 1 of chemotherapy and not more frequently than once every 14 days. Sustol® was found to be non-inferior to palonosetron IV in the acute and delayed phases of MEC and of AC combination therapy. Granisetron is currently available as a transdermal system (with the brand name of Sancuso®), tablets, and injection for intravenous use. There is no evidence at this time to support that Sustol® is safer or more effective than the currently available, more cost effective medications.

Recommendation:

- Add Sustol® injection 10mg/0.4ml with quantity limit 4 injections per 28 to non-preferred.
- Change quantity limit for Sancuso® to 4 patches/28 days.
    - Clinical criteria
        - Sustol: patient has a diagnosis of nausea and vomiting associated with cancer chemotherapy or radiotherapy AND prescriber provides documentation of medical necessity for the specialty dosage form (i.e. inability to swallow tablets, dysphagia) AND the patient has a documented side effect, allergy, or treatment failure with Ondansetron injection and Sancuso transdermal.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

g) Yosprala® (omeprazole & aspirin)

Yosprala® is indicated for patients who require aspirin for secondary prevention of cardiovascular and cerebrovascular events and who are at risk of developing aspirin associated gastric ulcers. The aspirin component of Yosprala® is indicated for:

- Reducing the combined risk of death and non-fatal stroke in patients who have had ischemic stroke or transient ischemia of the brain due to fibrin platelet emboli
- Reducing the combined risk of death and non-fatal MI in patients with a previous MI or unstable angina pectoris

- Reducing the combined risk of MI and sudden death in patients with chronic stable angina pectoris
- Use in patients who have undergone revascularization procedures (Coronary Artery Bypass Graft [CABG] or Percutaneous Transluminal Coronary Angioplasty [PTCA]) when there is a pre-existing condition for which aspirin is already indicated

The omeprazole component of Yosprala® is indicated for decreasing the risk of developing aspirin-associated gastric ulcers in patients at risk for developing aspirin-associated gastric ulcers due to age or documented history of gastric ulcers. Yosprala® contains a delayed-release formulation of aspirin and it is not for use as the initial dose of aspirin therapy during onset of acute coronary syndrome, acute myocardial infarction or before percutaneous coronary intervention (PCI), for which immediate-release aspirin therapy is appropriate. Yosprala® has not been shown to reduce the risk of GI bleeding due to aspirin, and it is not interchangeable with the individual components of aspirin and omeprazole. There is no evidence at this time to support that Yosprala® is safer or more effective than the currently available, more cost effective alternatives, including taking the combination of the individual ingredients.

Recommendation:

- Add Yosprala® to non-preferred.
  - Clinical criteria
    - Add Yosprala: The patient must be at risk for developing aspirin-associated gastric ulcers (history of gastric ulcers or age ≥ 60) AND the patient must have a documented side effect, allergy, or contraindication to 3 preferred PPI's (one of which must omeprazole) used in combination with aspirin.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

9. Therapeutic Drug Classes – Periodic Review: Laureen Biczak, DO, Change Healthcare and Laurie Brady, RPh, Change Healthcare

a) Hypoglycemics, Incretin Mimetics/enhancers

- Adlyxin® is a new medication in this class. It is a glucagon-like peptide-1 (GLP-1) receptor agonist. It increases glucose-dependent insulin release, decreases glucagon secretion, and slows gastric emptying. Adlyxin® is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus (DM). Adlyxin® is not a substitute for insulin and is not indicated for use in patients with type 1 DM or for the treatment of diabetic ketoacidosis. The concurrent use of Adlyxin® with short-acting insulin has not been studied and is

not recommended. It is recommended to consider other antidiabetic therapies in patients with a history of pancreatitis. It has not been studied in patients with gastroparesis and is not recommended for use in this population.

- Soliqua® is a new medication in this class. It is a combination product containing insulin glargine (a long-acting basal insulin analog) and lixisenatide (a glucagon-like peptide-1 [GLP-1] receptor agonist. It is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus (DM) inadequately controlled on basal insulin (less than 60 units QD) or lixisenatide. Soliqua® has not been studied in patients with a history of pancreatitis; thus, it is recommended to consider other antidiabetic therapies in patients with a history of pancreatitis. It has not been studied in patients with gastroparesis and thus use in this population is not recommended. It is not recommended for use in combination with any other product containing lixisenatide or another GLP-1 receptor agonist. Soliqua® is not indicated for use in patients with type 1 DM or for the treatment of diabetic ketoacidosis. Last, Soliqua® has not been studied in combination with prandial insulin.
- New indication for Jardiance to reduce the risk of cardiovascular death in adult patients with type 2 diabetes.

Recommendation:

Dipeptidyl Peptidase (DDP-4) Inhibitors

- Clinical criteria
  - Remove Janumet XR and Jentadueto XR criteria and combine to say: Janumet XR, Jentadueto XR: patient is unable to take Januvia or Tradjenta in combination with Metformin XR as the individual separate agents.
  - Revise Jentadueto criteria to say: Jentadueto: patient has had an inadequate response with Tradjenta OR Metformin monotherapy OR patient has been started and stabilized on Tradjenta and Metformin combo therapy.

Peptide Hormones

- Add Adlyxin® to non-preferred.
- Add Soliqua® with a quantity limit of 3pens/25 days to non-preferred.
- On preferred category heading, remove Incretin Mimetics replace with “GLP-1 Receptor Agonists SINGLE AGENTS.”
- Add to preferred a category heading of “COMBINATION AGENTS” and indicate that all products require PA.
  - Clinical criteria
    - Add Adlyxin to Trulicity/Tanzeum criteria
    - Add Soliqua: patient has a diagnosis of type 2 diabetes AND patient is at least 18 years of age AND patient has had a documented side effect, allergy, contraindication or treatment failure with metformin AND patient cannot achieve glycemic

control (defined as hemoglobin A1c ≤ 7%) with a preferred GLP-1 receptor agonist and Lantus used in combination.

Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors and Combinations

- Add Invokamet XR to non-preferred
  - Clinical criteria
    - Revise criteria for Invokamet/Invokamet XR/Xigduo XR additional criteria: The patient has documentation of a failure of therapy with Synjardy or with Jardiance used in combination with metformin/metformin XR.

Public Comment: David Conak, Sanofi; Highlighted attributes of Adlyxin and Soliqua.
Shaffee Bacchus, Janssen; Highlighted attributes of Invokamet XR.

Board Decision: The Board unanimously approved the above recommendation.

b) Hypoglycemics, Insulins & Related Agents

- Basaglar® is a new insulin glargine U-100 product. It is a long-acting basal insulin and is a recombinant human insulin analog. Insulin glargine regulates glucose metabolism. It stimulates peripheral glucose uptake and inhibits hepatic glucose production. Basaglar® is indicated to improve glycemic control in adults and pediatric patients with type 1 diabetes mellitus (DM) and in adults with type 2 DM. It is not recommended for the treatment of diabetic ketoacidosis. All insulin-containing products, including Basaglar®, can possibly cause hypokalemia. It is recommended to monitor potassium levels in patients at risk for hypokalemia. Per the FDA, Basaglar® "...is the first insulin product approved through an abbreviated approval pathway under the Federal Food, Drug, and Cosmetic Act..." and an "...application was submitted for Basaglar® that relied, in part, on the FDA's finding of safety and effectiveness for Lantus® to support approval. Basaglar® was "...sufficiently similar to Lantus® to scientifically justify reliance, and also provided Basaglar® specific data to establish the drug's safety and efficacy for its approved uses." The FDA does not consider Basaglar® to be a biosimilar and it is not approved as a biosimilar product.
- A 2016 network meta-analysis by Freemantle et al[194] included 41 randomized controlled trials to assess the safety and efficacy of insulin glargine 300 U/ml as compared with other basal insulin therapies in patients with type 2 DM. Outcomes assessed were changes in HbA1c and body weight, as well as rates of nocturnal and documented symptomatic hypoglycemia. Results suggested that in patients with type 2 DM on BOT, the change in HbA1c was comparable between insulin glargine.
- A 2016 Cochrane Review by Fullerton included 9 randomized controlled trials to assess the efficacy of short-acting insulin analogues as compared with regular human insulin when used in adults with type 1 DM. While the data was of low

quality in regards to overall hypoglycemia, significant differences were not seen between groups.

Recommendation:

- Add Basaglar® to non-preferred.
  - Clinical criteria
    - Revise Toujeo criteria to say: TOUJEO: Diagnosis of diabetes mellitus AND Prescription is initiated in consultation with an Endocrinologist AND The patient is currently on insulin glargine U100 and cannot achieve glycemic control (defined as hemoglobin A1c ≤ 7%) because dose increases cannot be tolerated despite attempts at manipulating dosing time or splitting the dose and the volume at the injection site for each dose exceeds 1ml. Note: Pharmacy claims will be evaluated to assess compliance with insulin glargine U100 therapy prior to Toujeo approval.
    - Revise Tresiba flextouch criteria to say: TRESIBA FLEXTOUCH: Diagnosis of diabetes mellitus AND prescription is initiated in consultation with an Endocrinologist AND the patient must have documented treatment failure with BOTH preferred long-acting agents AND For approval of U200, the patient must be currently on Tresiba U100 and cannot achieve glycemic control (defined as hemoglobin A1c ≤ 7%) despite attempts at manipulating dosing time or splitting the dose and the volume at the injection site for each dose exceeds 1ml.
    - Add BASAGLAR: Diagnosis of diabetes mellitus AND prescription is initiated in consultation with an Endocrinologist AND the patient cannot achieve glycemic control (defined as hemoglobin A1c ≤ 7%) despite a 5-year trial of Lantus. Note: Pharmacy claims will be evaluated to assess compliance with Lantus therapy prior to Basaglar approval.
    - Remove the Diabetes Mellitus Type 2 additional criteria.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation with the amendment that initial approval for Toujeo, Tresiba and Basaglar should be for 6 months. For continuation of approval after 6 months, the patient must have demonstrated improvement in Hemoglobin A1c of ≥ 0.5%.

c) Hypoglycemics, Meglitinides

- No new drugs.
- No significant changes.
- A 2016 Cochrane Review by Hemmingsen included 6 randomized controlled trials to assess the efficacy of insulin secretagogues on the prevention of delay of

type 2 DM and its associated complications in those with impaired glucose tolerance, impaired fasting blood glucose, moderately elevated HbA1c, or any combination of these. There was one trial with a 5-year follow-up that compared nateglinide with placebo. The authors concluded that there was insufficient evidence to demonstrate if insulin secretagogues reduced the risk of developing type 2 DM and its associated complications as compared with placebo.

Recommendation:

- Move repaglinide to preferred.
- Add under preferred combination sub-category that All products require PA.
- Add Repaglinide/metformin to non-preferred agents.
- Remove Prandimet from the PDL as it is no longer available or rebateable.
    - Clinical criteria
        - Revise to say: Prandin, Starlix: patient has had a documented intolerance to the generic equivalent.
        - Revise to say: Repaglinide/metformin: patient is unable to take repaglinide and metformin as the individual separate agents.
        - Remove all other criteria.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

d) Hypoglycemics, TZD's

- No new drugs.
- No significant changes.
- In 2016, the FDA issued a Safety Communication regarding pioglitazone-containing medications and an updated FDA review on the risk of bladder cancer.

Recommendation:

Thiazolidinediones

- Remove Avandamet from non-preferred as it is no longer available.
- Remove Avandaryl from non-preferred as it is no longer available.

Alpha-Glucosidase Inhibitors

- No changes at this time.

Biguanides & Combinations

- Move Riomet to non-preferred.
- Remove Metaglip from non-preferred.

- Clinical criteria
  - Riomet: prescriber provides documentation of medical necessity for the specialty dosage form (i.e. inability to swallow tablets, dysphagia).

Sulfonylureas 2nd Generation

- Remove Diabeta from non-preferred as it is no longer available.
- Remove Micronase from non-preferred as it is no longer available.
  - Clinical criteria
    - Revise criteria to say: Patient must have a documented side effect, allergy or treatment failure to two preferred sulfonureas. If a product has an AB rated generic, one trial must be the generic.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

e) Immunosuppressive (oral)

- No new drugs.
- No significant changes.
- Used mostly in solid-organ transplantation, these agents provide a lifesaving treatment for patients with end-stage kidney, liver, and heart disease. In 2016, 33,595 solid organ transplants were performed in the United States. Kidney transplants are the most common; 13,430 from deceased donors and 5,629 from living donors in 2016.

Recommendation:

- Add AZATHIOPRINE tablet to preferred.
- Add CYCLOSPORINE capsule to preferred.
- Add CYCLOSPORINE MODIFIED to preferred.
- Add MYCOPHENOLATE MOFETIL tablet, capsule, suspension to preferred.
- Add MYCOPHENOLIC ACID delayed release tablet to preferred.
- Add SIROLIMUS tablet to preferred.
- Add TACROLIMUS capsule to preferred.
- Add ZORTRESS tablet to preferred.
- Add Astagraf® XL to non-preferred.
- Add Azasan® tablet to non-preferred.
- Add Cellcept® tablet, capsule, suspension to non-preferred.
- Add Envarsus® XR tablet to non-preferred.
- Add Gengraf® capsule, solution to non-preferred.

- Add Imuran® tablet to non-preferred.
- Add Myfortic delayed release tablet to non-preferred.
- Add Neoral® capsule, solution to non-preferred.
- Add Prograf® capsule to non-preferred.
- Add Rapamune® tablet, solution to non-preferred.
- Add Sandimmune® capsule, solution to non-preferred.
    - Clinical criteria
        - The patient has been started and stabilized on the requested product OR the patient has a documented side effect, allergy, or treatment failure to a preferred agent (If a product has an AB rated generic, there must be a trial of the generic formulation).

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

f) Bladder Relaxants

- No new drugs.
- No significant changes.
- Interest in looking at combo verses single drugs.

Recommendation: No changes at this time.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

10. New Managed Therapeutic Drug Classes

- None at this time

11. General Announcements:

Selected FDA Safety Alerts

Drug Information Update - FDA releases final guidance for "Nonproprietary Naming of Biological Products"
https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM459987.pdf?source=govdelivery&utm_medium=email&utm_source=govdelivery

FDA Drug Safety Communication: FDA warns about increased risk of serious pancreatitis with irritable bowel drug Viberzi (eluxadoline) in patients without a gallbladder
https://www.fda.gov/Drugs/DrugSafety/ucm546154.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

FDA Drug Safety Communication: FDA revises description of mental health side effects of the stop-smoking medicines Chantix (varenicline) and Zyban (bupropion) to reflect clinical trial findings
https://www.fda.gov/Drugs/DrugSafety/ucm532221.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

12. Adjourn: Meeting adjourned at 8:35 p.m.